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August 4, 2021
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Antibe Therapeutics Inc.

(OTCQX: ATBPF)

ATBPF: Unexpected Liver Enzyme Elevations Leads to Pause in AME Trial…

Based on our probability adjusted DCF model that takes into account potential future revenues from otenaproxesul, ATBPF is valued at $4.75 per share. This model is highly dependent upon continued clinical success of otenaproxesul and will be adjusted accordingly based upon future clinical results and the company's execution.

Current Price (08/04/2021)	$0.81
Valuation	**$4.75**

OUTLOOK

On August 3, 2021, Antibe Therapeutics Inc. (ATBPF) provided an update on the company's absorption, metabolism, and excretion (AME) study of otenaproxesul. Due to a pre-specified safety threshold being exceeded, the company has placed the study on pause. A total of 42 subjects were enrolled to receive daily doses of 75 mg or 100 mg of otenaproxesul, with 35 completing the 28-day administration period and seven completing 21 days of administration. Three subjects from the 100 mg cohort experienced liver transaminase elevations >5X the upper limit of normal. Antibe will continue to collect data over the pre-specified 14-day post-administration observation period and then analyze all the data from the trial to try to understand the cause of the transaminase elevations.

SUMMARY DATA

52-Week High	**$5.54**
52-Week Low	**$0.81**
One-Year Return (%)	**-73.01**
Beta	**0.51**
Average Daily Volume (sh)	**41,955**
Shares Outstanding (mil)	**52**
Market Capitalization ($mil)	**$42**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using #Lin Estimate	**N/A**
P/E using #Lin Estimate	**N/A**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2021	0.9 A	2.2 A	2.2 A	2.2 A	7.7 A
2022	2.2 E	2.2 E	2.2 E	2.2 E	8.8 E
2023					9.0 E
2024					9.2 E

Earnings per Share

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2021	-$0.12 A	-$0.16 A	-$0.13 A	-$0.02 A	-$0.56 A
2022	-$0.09 E	-$0.09 E	-$0.09 E	-$0.10 E	-$0.38 E
2023					-$0.35 E
2024					-$0.33 E

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WHAT'S NEW

Business Update

Phase 3 Program for Otenaproxesul on Pause

On August 3, 2021, Antibe Therapeutics, Inc. (ATBPF) announced that the absorption, metabolism, and excretion (AME) study of otenaproxesul has been paused due to a pre-specified safety threshold being exceeded. The study had enrolled a total of 42 subjects that were randomized to receive either 75 mg or 100 mg of otenaproxesul daily, of whom 35 had completed the full 28 days of dosing and seven had completed 21 days of dosing. Following completion of the 28-day administration period, three of the subjects in the 100 mg cohort exhibited liver transaminase levels that were >5X the upper limit of normal (ULN), which is what triggered the pause in the trial.

The news of liver transaminase elevations is very unexpected as this was not previously seen in any of the long-term animal toxicology studies. And while the liver transaminase elevations are concerning, there were no elevations in other liver tests, thus there are no Hy's Law concerns. In addition, none of the patients with elevated liver transaminase levels had any signs of clinical illness and all were asymptomatic.

Since all subjects in the study were housed at the clinical research center for the entire duration of dosing any outside influences that could have affected liver transaminase levels can be ruled out, thus pointing to a drug-specific phenomenon. However, the only patients with large increases in liver transaminase levels were in the 100 mg cohort, thus it also appears as though it is a dose-dependent effect.

The study has a pre-specified 14-day post-administration observation period that is currently ongoing. The company is continuing to collect blood samples from all study subjects during the observation period to determine the extent of the liver transaminase increases, including their duration. In addition, the level of COX inhibition will be examined through biomarkers such as TxB2 and PGE_2. Following the completion of the observation period, Antibe will evaluate all of the available data from the study in an effort to better understand the cause of the liver transaminase elevations. The company will also be requesting a meeting with Health Canada regarding the development path for otenaproxesul once all of the data has been collected and analyzed. The timing of this meeting is still not known; however, it is possible it could occur before the end of 2021.

While the future of otenaproxesul is currently uncertain, we believe there is still a potential path forward for the program. We anticipate the company approaching Health Canada with a plan to perform an additional AME study testing lower doses of the drug, which may also include a 75 mg cohort (assuming no liver transaminase elevations are seen in that cohort during the current observation period). As a reminder, the results of the Phase 2b efficacy trial showed that the 150 mg dose of otenaproxesul had robust efficacy in the primary endpoint and missed being statistically significant due to that arm of the trial not being properly powered. Thus, a lower dose may still offer sufficient efficacy, however that dose would have to be less than 100 mg (with additional insight into this possibility being obtained from the COX inhibition data). Ultimately, the path forward for otenaproxesul will not be determined until after the company is able to meet with Health Canada, thus we don't anticipate any clarity until that meeting is able to occur.

Conclusion

The surprising news of a pause in the AME study is very disappointing as the future for otenaproxesul is much less clear now. We anticipate the company providing additional updates as warranted as the year goes on in regards to data collection/analysis along with the timing of the meeting with Health Canada. Based on this news we have made several adjustments to our model, including lowering the probability of approval to 25%, pushing out anticipated approval by one year, and lowering peak revenue projections by 50%. Due to these changes, our valuation is now $4.75 per share.

PROJECTED FINANCIALS

Antibe Therapeutics Inc.
Income Statement

Antibe Therapeutics, Inc. Year Ends Mar. 31 / in US Dollars	FY 2020 A	Q1 '21 A	Q2 '21 A	Q3 '21 A	Q4 '21 E	FY 2021 E	FY 2022 E	FY 2023 E
Otenaproxesul	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
ATB-352 (royalty)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Citagenix	$7.6	$0.9	$2.2	$2.2	$2.0	$7.4	$8.7	$8.7
Licensing / Development	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	$7.5	$0.9	$2.2	$2.2	$2.0	$7.4	$8.7	$8.7
YOY Growth	*3.5%*	*-42.2%*	*20.5%*	*5.5%*	*5.2%*	*-1.3%*	*13.6%*	*0.0%*
Cost of Goods Sold	$4.6	$0.5	$1.5	$1.3	$1.3	$4.6	$5.5	$5.5
Product Gross Margin	*29%*	*32%*	*25%*	*33%*	*28%*	*30%*	*29%*	*29%*
SG&A	$7.1	$1.7	$2.4	$2.2	$2.1	$8.5	$7.3	$7.5
R&D	$6.1	$1.6	$3.8	$2.7	$1.9	$10.0	$7.1	$7.9
Stock-based compensation	$2.5	$0.8	$0.6	$0.6	$0.6	$2.4	$2.4	$2.4
Impairment of goodwill	$1.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Amortization and Depreciation	$0.4	$0.1	$0.1	$0.1	$0.1	$0.4	$0.4	$0.4
% Other	*4.3%*	*8.5%*	*3.8%*	*2.9%*	*3.9%*	*4.2%*	*3.6%*	*3.6%*
Operating Income	($14.2)	($3.7)	($6.2)	($4.7)	($4.0)	($18.5)	($14.0)	($14.9)
Operating Margin	-142%	-304%	-215%	-168%	-159%	-198%	-127%	-136%
Interest Income / Net	($0.3)	($0.0)	$0.0	$0.0	($0.2)	($0.6)	($0.6)	($0.6)
Pre-Tax Income	($14.5)	($3.7)	($6.1)	($4.7)	($4.1)	($19.2)	($14.6)	($15.6)
Taxes	($0.0)	$0.0	$0.0	$0.0	$0.0	$0.0	($0.0)	($0.0)
Tax Rate	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*
Net Income	($14.5)	($3.7)	($6.1)	($4.7)	($4.1)	($19.2)	($14.6)	($15.5)
Loss from Discontinued Operations	$0.0	$0.0	($0.7)	($0.4)	$0.0	($1.2)	$0.0	$0.0
Comprehensive Loss	($14.5)	($3.7)	($6.6)	($4.9)	($3.9)	($19.1)	($13.9)	($14.8)
Reported EPS	($0.53)	($0.12)	($0.18)	($0.13)	($0.11)	($0.52)	($0.32)	($0.31)
Fully Diluted Shares	27.3	30.3	38.6	38.6	39.0	36.6	45.0	50.0

Source: David Bautz, PhD - Zacks Investment Research, Inc.

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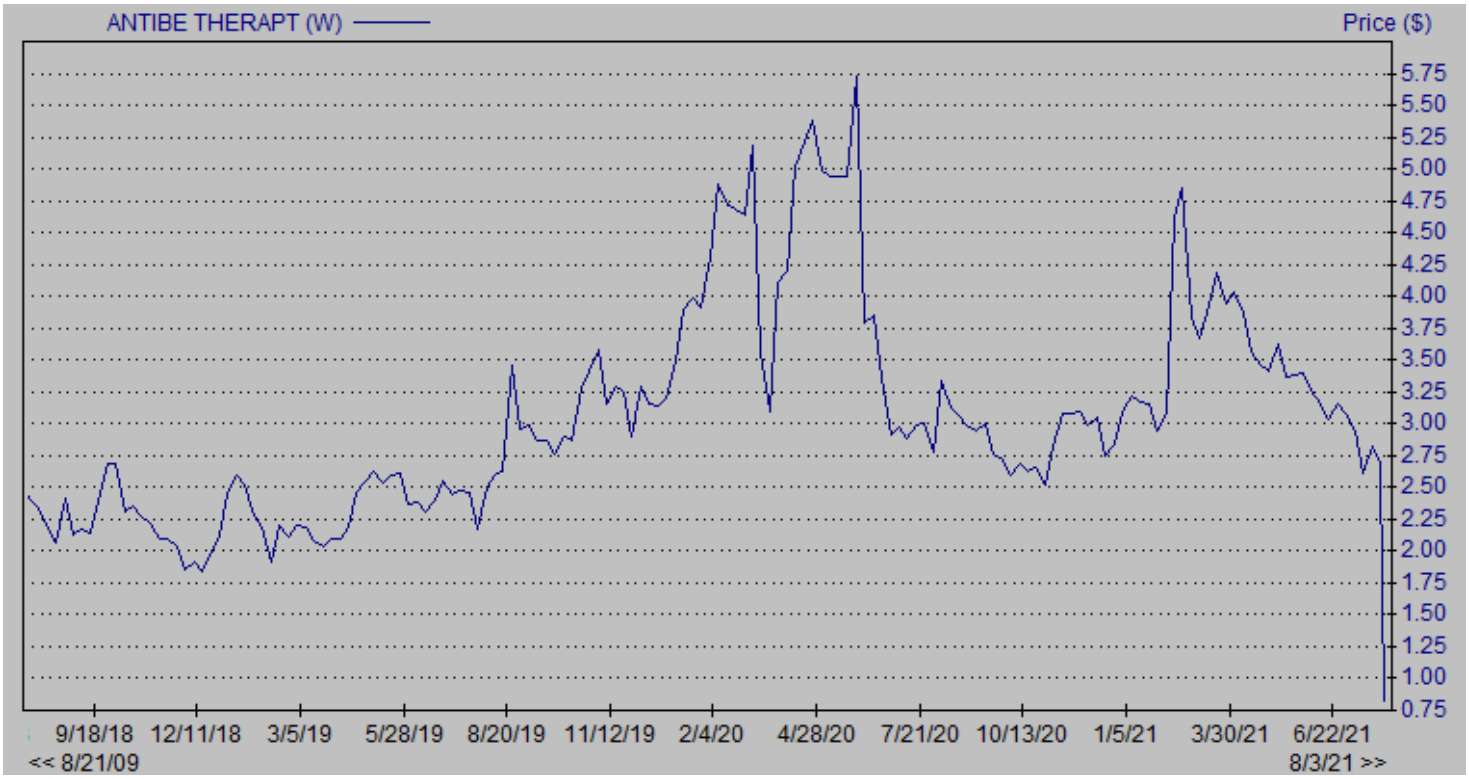

Source: Zacks Small Cap Research

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